

COMMONWEALTH OF VIRGINIA
Department of Environmental Quality
Valley Regional Office

STATEMENT OF LEGAL AND FACTUAL BASIS

Merck & Co., Inc. (Stonewall Plant)
4 miles South of Elkton on VA Route 340
Rockingham County, Virginia

Permit Number: VRO80524

Title V of the 1990 Clean Air Act Amendments required each state to develop a permit program to ensure that certain facilities have federal Air Pollution Operating Permits, called Title V Operating Permits. As required by 40 CFR Part 70 and 9 VAC 5 Chapter 80, Merck & Co., Inc. (Stonewall Plant) has applied for a Title V Operating Permit for its pharmaceutical manufacturing facility. The Department has reviewed the application and has prepared a draft Title V Operating Permit.

Engineer/Permit Contact: _____ Date: _____

Air Permit Manager: _____ Date: _____

Regional Permit Manager: _____ Date: _____

FACILITY INFORMATION

Permittee

Merck & Co., Inc. (Stonewall Plant)
P. O. Box 7
Elkton, Virginia 22827

Facility

Merck & Co., Inc. (Stonewall Plant)
4 miles South of Elkton on VA Route 340
Rockingham County, Virginia

NET ID No: 51-165-0001

SOURCE DESCRIPTION

SIC 2833 – Medicinal Chemicals and Botanical Products
SIC 2834 – Pharmaceutical Preparations

Merck & Co., Inc. (Stonewall Plant) is involved in the manufacture of various pharmaceutical intermediates and products.

The facility is currently a Title V major source of SO₂, NO_x, VOC, and HAPs. This source is located in an attainment area for all pollutants, and is a PSD major source. The facility was previously permitted under a PSD permit (Project XL) issued on January 7, 1998 and amended on August 8, 2001.

COMPLIANCE STATUS

The facility is inspected once a year.

Merck & Co., Inc. (Merck) was last inspected on September 25, 2000, and found to be in compliance.

EMISSION UNIT AND CONTROL DEVICE IDENTIFICATION

The emissions units at this facility consist of the following:

Table I. Significant Emission Units.

Emission Unit ID	Emission Unit Description	Applicable Permit Date
B	Powerhouse: <ul style="list-style-type: none"> - distillate oil-fired boiler (backup unit) (4) - two natural gas-fired boilers (with distillate oil or propane backup) (7 & 8) 	2/10/1998 amended 8/8/2001
C	Sludge Incinerator	2/10/1998 amended 8/8/2001
D	Internal Combustion Engines	2/10/1998 amended 8/8/2001
E	Production Process Units	2/10/1998 amended 8/8/2001
F	Sludge Dryer	2/10/1998 amended 8/8/2001

EMISSIONS INVENTORY

A copy of the 2000 annual emission update is attached as Attachment A. Emissions are summarized in the following tables.

Table II. 2000 Actual Criteria Pollutant Emissions.

	Criteria Pollutant Emissions (tons/yr)				
	VOC	CO	SO ₂	PM-10	NO _x
Facility-Wide	91	20	270	23	168

Table III. 2000 Actual Hazardous Air Pollutant Emissions.

Pollutant	Hazardous Air Pollutant Emissions (tons/yr)
Hydrochloric Acid (CAS # 7647-01-0)	26
Cyanide Compounds	2
Hydrofluoric Acid (CAS # 7664-39-3)	3
Miscellaneous non-VOC, non-	0.25

PM HAPs	
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EMISSION UNIT APPLICABLE REQUIREMENTS

Merck is currently operating under a PSD permit, dated January 7, 1998 with an amended date of 8/8/2001. All section numbers are from the PSD permit; a copy of the permit is included as Attachment B. The Federal and State rulemakings to support the PSD permit can be found in Attachments C and D, respectively.

Facility Wide Conditions (Project XL)

Limitations

Section 1 from the PSD permit (Site-wide Emission Caps) has been incorporated into the Title V permit.

40 CFR 60.49b(u)(1)(i), a requirement in NSPS Subpart Db, requires that low NO_x technology be installed on the natural gas-fired boilers in the powerhouse. This requirement has been incorporated into the Title V permit. Also, the approved fuels for the boilers have been included.

Monitoring and Recordkeeping

The monitoring, recordkeeping, and reporting requirements in Section 4 of the PSD permit have been incorporated and meet Part 70 requirements.

40 CFR 60.49b(u)(1)(ii), a monitoring requirement in NSPS Subpart Db, requires Merck to operate a continuous emissions monitoring system or a predictive emissions monitoring system for NO_x emissions from the natural gas-fired boilers. This requirement has been incorporated into the Title V permit.

Section 4 of the PSD permit dictates all of the required monitoring, recordkeeping, and reporting requirements for all of the applicable requirements in the permit. A tiered approach is utilized such that the requirements increase as Merck begins to operate at levels closer to the caps. The monitoring and recordkeeping that are in the PSD permit, and have been incorporated into the Title V permit, satisfy the periodic monitoring requirement for all applicable requirements in the permit.

The State Rulemaking that is applicable to Merck (a copy of which can be found in Attachment D) states that the monitoring in the PSD permit satisfies the monitoring requirements in 9 VAC 5-80-110E. Therefore, the monitoring in the Title V operating permit satisfies the periodic monitoring requirements for the facility.

Reporting

The reporting requirements from Section 4 of the PSD permit have been moved into their own section. This will allow Merck and DEQ staff to more easily identify the reporting requirements.

Testing

The permit requires performance testing on certain units when Tier III monitoring/reporting is reached. A table of test methods has been included in the permit if testing is performed. The Department and EPA have authority to require testing not included in this permit if necessary to determine compliance with an emission limit or standard.

Streamlined Requirements

The following Section was not incorporated into the Title V permit because the requirements have been completed. Please note that section numbers refer to those found in the PSD permit, a copy of which is included as Attachment B.

Section 5 - Merck is operating under the emission caps. Therefore, the requirements have been fulfilled and are no longer required.

Facility Wide Conditions (Visible Emissions & MACT)

Limitations

The PSD permit did not contain any visible emission limitations. Therefore, the following requirements have been added to the permit:

9 VAC 5-40-80: Standard for Visible Emissions

9 VAC 5-50-80: Standard for Visible Emissions.

The PSD permit did not address the Pharmaceutical MACT and a requirement for compliance with the MACT has also been added (see FUTURE APPLICABLE REQUIREMENTS section of this document for further information).

Monitoring

40 CFR 60.49b(u)(1)(ii), a monitoring requirement in NSPS Subpart Db, requires Merck to operate a continuous emissions monitoring system or a predictive emissions monitoring system for visible emissions from the natural gas-fired boilers. This requirement has been

incorporated into the Title V permit.

The PSD permit did not address visible emission requirements and those limitations had to be added as part of the Title V permit. The visible emission limit established in the permit was established for all process unit stacks with the potential to emit particulate matter. Merck will be required to perform monthly visible emission checks on each process unit stack that has the potential to emit particulate matter. Those stacks that do not emit particulate matter will most likely be pure VOC streams, meaning that no visible emissions are expected. If visible emissions are present on any of the stacks that are observed, six minute visible emission evaluation must be performed unless corrective action can be taken such that the stack is returned to no visible emissions. If during the six minutes, any violations of the 20% opacity standard are noted, a one hour visible emission evaluation is required to demonstrate compliance with the standard. If 12 monthly inspections are performed on any given stack, and no visible emissions are present, then the visible inspections may be performed quarterly. However, as soon as visible emissions are noted during a quarterly inspection, the inspections must then be performed monthly again. This requirement satisfies the periodic monitoring requirement for the opacity standards on the process unit stacks with the potential to emit particulate matter.

Recordkeeping

Merck will be required to keep records as required for the opacity monitor on the natural gas-fired boilers and the visible emission evaluations on process unit stacks with the potential to emit particulate matter.

Testing

The permit does not require source tests. A table of test methods has been included in the permit if testing is performed. The Department and EPA have authority to require testing not included in this permit if necessary to determine compliance with an emission limit or standard.

Administration of PSD (Project XL) Permit

The following Sections of the PSD permit dealt only with the administration of the PSD permit. As such, they have been included in a section of the Title V permit that has been devoted to Administration of the PSD permit.

Section 6 - Periodic Review of the PSD Permit

Section 7 - Duration of the PSD Permit

Section 8 - Termination of the PSD Permit

Section 9 - Inspection and Entry

Section 10 - Reservation of Rights

Section 11 - Transfer of Ownership

Section 12 - Definitions for Terms in the PSD Permit

Streamlined Requirements

The following Section was not incorporated into the Title V permit because the requirements have been completed. Please note that section numbers refer to those found in the PSD permit, a copy of which is included as Attachment B.

Section 8.1.3 - The powerhouse conversion has been completed.

Compliance with State and Federal Regulations and Air Permits Under PSD (Project XL) Permit

Sections 2 and 3 of the PSD permit have been included in Section VII of the Title V permit as the means for complying with applicable state and federal regulations.

Streamlined Requirements

Parts of the following Sections were not incorporated into the Title V permit because the requirements have been completed. Please note that section numbers refer to those found in the PSD permit, a copy of which is included as Attachment B.

Sections 2.1, 2.2, and 2.3 - The powerhouse conversion has been completed.
Section 3.1 - List of preconstruction permits replaced by PSD permit.
Section 4.3.2 - PM-10 cap adjustment has been completed.

PERMIT AMENDMENT

While drafting the Title V permit, Merck requested that several minor changes be made to their PSD permit. All requested changes can be made through the administrative permit modification procedure contained in 9 VAC 5-190-80D. Following is a summary of these changes.

<u>Permit Section</u>	<u>Summary of Change</u>
Section 1.2.1 (c)	PM-10 emission cap adjusted to 46 tons per year.
Section 3.1	List of superseded permits updated to include those issued or modified subsequent to the issuance of the PSD permit and prior to the effective date of the permit.

Section 4.9	“Prevented” changed to “reduced” to match the change made in the clarification of reporting requirements in Table 4.2 (A.8 and A.9).
Section 12.5	Clarified the definition of Process Unit by changing “and” to “or.”
Table 1.3.3	<p>Solid waste incinerator deleted. This unit has undergone formal closure.</p> <p>Deleted DC-383 and DC-384 and added DC-609 for the sludge dryer to correspond to changes made in the permit dated 7/17/2000.</p> <p>Description of solvent recovery scrubber changed from “Venturi scrubber” to “Venturi/packed bed scrubber.”</p>
Table 4.2	<p>Requirements for cap calculations clarified in A.8 and A.9.</p> <p>References to solid waste incinerator deleted as unit has been formally shut down.</p> <p>Monitoring requirements for emergency powerhouse diesel generator (D.7) changed based on DEQ letter dated 2/1/99 which accepts the timing set by the manufacturer.</p> <p>Deleted DC-383 and DC-384 and added DC-609 for the sludge dryer to correspond to changes made in the permit dated 7/17/2000.</p> <p>Description of solvent recovery scrubber changed from “Venturi scrubber” to “Venturi/packed bed scrubber.”</p>
Table 4.3	<p>Deleted “MacEMIT” and “EMIT 10” and added the “1994 ACT” to more accurately describe the method of calculation rather than the specific tools used to implement the methods.</p> <p>Added Method No. 6, EPA AP-42 Emission Factors, as an additional method for calculation of VOC emission from bulk storage tanks.</p>
Table 12.8	Updated the table of project signatory representatives by substituting Michael A. Breeden for William Kyger as Chairman of the Rockingham County Board of Supervisors.

This permit amendment will be issued contemporaneously with the proposed Title V permit.

GENERAL CONDITIONS

The permit contains general conditions required by 40 CFR Part 70 and 9 VAC 5-80-110, that apply to all Federal operating permit sources. These include requirements for submitting an annual compliance certification report. The permit also requires notification of deviations from permit requirements or any excess emissions, including those caused by upsets, within one business day.

Several of the General Conditions that are normally included in Virginia's Title V operating permits are not applicable to Merck – either because the Variance (9 VAC 5 Chapter 190) explicitly states that they are not applicable or because they contradict with conditions in the PSD permit. The following General Conditions have been omitted from Merck's Title V operating permit. Please note that condition numbers refer to those found in the Title V operating permit boilerplate.

Omitted because they are not applicable:

Condition C: Recordkeeping and Reporting

Condition J: Permit Action for Cause (the requirements that did not pertain to Merck have been removed)

Condition O: Startup, Shutdown, and Malfunction

Condition Q: Inspection and Entry Requirements

Omitted because they contradict with conditions in the PSD permit:

Condition Z: Changes to Permits for Emissions Trading

Condition AA: Emissions Trading

STATE ONLY APPLICABLE REQUIREMENTS

Merck did not identify any state-only enforceable requirements in their application, and all requirements in the PSD permit are federally enforceable. Therefore, no state-only applicable requirements have been included in the permit.

FUTURE APPLICABLE REQUIREMENTS

Merck is currently a major source of hazardous air pollutants, and is subject to 40 CFR 63, Subpart GGG, National Emission Standards for Hazardous Air Pollutants for Pharmaceuticals Production. The MACT has been promulgated, and existing sources must be in compliance with the MACT no later than October 21, 2002. Currently, Merck has determined that it will comply with the MACT by securing federally enforceable limits to become a synthetic minor source for HAPs. As such, a condition has been added to Section IV of the permit stating that they must be in compliance with the MACT as stated in 40 CFR 63.1250.

INAPPLICABLE REQUIREMENTS

Merck did not identify any inapplicable requirements in their application. Therefore, no inapplicable requirements are included in the permit.

COMPLIANCE PLAN

Merck is currently in compliance with all applicable requirements. No compliance plan was included in the application or in the permit.

INSIGNIFICANT EMISSION UNITS

Merck did not identify any insignificant emission units in their application. Therefore, no insignificant emission units are included in the permit.

CONFIDENTIAL INFORMATION

Merck did not submit a request for confidentiality. Therefore, all portions of the Title V application are suitable for public review.

PUBLIC PARTICIPATION

A public notice regarding the draft permit was placed in the Daily News Record, Harrisonburg, Virginia, on July 20, 2001. EPA was sent a copy of the draft permit and notified of the public notice on July 19, 2001 and concurrently reviewed the draft permit as a proposed permit. West Virginia, the only affected state, was sent a copy of the public notice in a letter dated July 20, 2001. All persons on the Title V mailing list were also sent a copy of the public notice in letters dated July 20, 2001.

Public comments were accepted from July 20, 2001, to August 20, 2001. No comments were received from the public, EPA, or West Virginia regarding the draft permit. Merck sent comments in a letter dated August 17, 2001 requesting delaying issuance of the initial Title V permit. Response to Merck's comments can be found in a DEQ letter dated August 31, 2001.

Merck & Co., Inc. (Stonewall Plant)

Permit Number: VRO80524

Statement of Basis

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Attachment A

2000 Annual Emission Update

Attachment B

PSD Permit
January 7, 1998
Amended
August 8, 2001

Attachment C

Federal Rule
40 CFR 52.2454

Attachment D

State Rule 9 VAC 5 Chapter 190